ORIGINAL ARTICLE

Bedside FibroScan as a Point-of-care Tool for Quantification for Cirrhosis: A Single-center Prospective Observational Study from Western India

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Abstract

Background: Cirrhosis, a major cause of global morbidity and mortality, necessitates early detection and accurate staging for optimal management. Traditional reliance on liver biopsy is being challenged by noninvasive techniques such as transient elastography (FibroScan®), which measures liver stiffness to estimate fibrosis severity. The potential for FibroScan® as a point-of-care (POC) tool supports rapid clinical decision-making in multiple clinical settings and scenarios.

Materials and methods: A prospective observational study was conducted from December 2024 to February 2025 at a tertiary center in Western India, enrolling adult patients with suspected liver disease, metabolic risk factors, or excessive alcohol consumption. Liver fibrosis was assessed using the Echosense FibroScan mini+430 device, applying the Metabolic Dysfunction-Associated Steatohepatitis (MASH) scoring system (F0–F4). At least 10 valid liver stiffness measurements (LSM) were obtained per patient. Data analysis included *t*-tests, analysis of variance (ANOVA), Chi-squared tests, and receiver operating characteristic (ROC) curve analysis for diagnostic accuracy.

Results: Of the 93 patients (mean age 52.3 years; 69.9% male), 41.9% had advanced fibrosis, and 30.1% demonstrated cirrhosis. Alcohol intake and diabetes were significantly associated with fibrosis stage ($p = 0.002$ and $p = 0.008$, respectively). FibroScan® showed excellent diagnostic accuracy for cirrhosis (AUROC = 0.91) and good accuracy for significant fibrosis (AUROC = 0.82); the optimal LSM cutoff for F4 was 12.5 kPa. Body mass index (BMI) correlated weakly but significantly with CAP values.

Conclusion: Bedside FibroScan® offers a highly accurate, rapid, and noninvasive method for quantifying liver fibrosis and cirrhosis in clinical practice. Its integration into routine care could substantially improve management for patients at risk of liver disease.

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Introduction

Cirrhosis of the liver is characterized by fibrosis, hepatocellular injury, and the eventual loss of liver function. It is one of the leading causes of morbidity and mortality worldwide.[1] Early detection and accurate assessment of liver fibrosis are critical for managing cirrhosis, as they guide treatment decisions, risk stratification, and surveillance for complications, including liver cancer and portal hypertension. Traditionally, the diagnosis and staging of cirrhosis have relied heavily on invasive liver biopsy, an expensive, uncomfortable, and potentially risky procedure for patients.[2] However, advances in noninvasive diagnostic techniques have revolutionized the management of cirrhosis, providing clinicians with effective alternatives to biopsy.

Among these noninvasive methods, elastography-based technologies have gained considerable attention. The FibroScan® (transient elastography) is a noninvasive diagnostic tool that measures liver stiffness, which correlates with the degree of fibrosis and cirrhosis.[3] By applying an external probe to the skin over the liver, FibroScan® uses low-frequency vibrations to assess the stiffness of liver tissue.[4] Higher liver stiffness indicates advanced fibrosis or cirrhosis. FibroScan® is validated as a reliable tool for quantifying liver stiffness, with several studies demonstrating its accuracy in distinguishing between different stages of liver disease.[5] It is particularly valued for its ability to provide rapid, real-time results with minimal discomfort to the patient, making it a highly attractive option for use in clinical practice.

Recently, there has been a growing interest in utilizing FibroScan® as a point-of-care (POC) tool, which allows for bedside assessment in a variety of clinical settings.[6] Bedside use of FibroScan® can provide immediate results, facilitating faster decision-making and improving patient management. For patients with known or suspected cirrhosis, the ability to quickly assess liver stiffness at the point of care can lead to more timely interventions, such as initiation of antiviral therapy, management of cirrhotic complications, or consideration for liver transplantation.[7] Additionally, bedside FibroScan® can help in the monitoring of disease progression, assessment of response to treatment, and evaluation of liver health in high-risk populations.[8]

This article explores the role of bedside FibroScan® as a POC tool for quantifying cirrhosis in patients with liver disease.[9] We review the current evidence supporting its use in clinical settings, highlight its advantages and limitations, and discuss how it can be integrated into routine care to improve the management of patients with cirrhosis.[10] By exploring these considerations, we aim to provide insights into the practical application of FibroScan® as an essential diagnostic tool in the era of noninvasive liver disease management.

Materials and Methods

This was a prospective observational study conducted from December 2024 to February 2025 at Smt. Kashibai Navale Medical College and General Hospital. Prior IEC clearance was obtained (Ref. SKNMC/Ethics/App/2024/311). All patients within this period who were compliant with the inclusion criteria were enrolled after prior informed consent.

Physics and Working of the FibroScan Device

Echosense FibroScan mini+430 equipment (Fig. 1) was used. A FibroScan machine works on the principle of transient elastography, which uses low-frequency ultrasound waves to create and measure shear waves in the liver. The operator first positions the

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patient on their back with the right arm raised behind their head, and then applies a water-based gel to the probe (Fig. 2). The probe is then placed between the patient's ribs to locate the liver, and the device sends a shear wave to measure liver stiffness in kPa. At least 10 valid measurements are recorded, and the results, which indicate liver scarring, are displayed on the machine's screen.[11]

Fibrosis was evaluated according to the metabolic dysfunction-associated steatohepatitis (MASH): Clinical Research Network Scoring System on a five-stage scale: F0 (no fibrosis), F1 (perisinusoidal or periportal fibrosis: 1A—mild, zone perisinusoidal; 1B—moderate, zone 3, perisinusoidal; 1C—portal/periportal), F2 (perisinusoidal and portal/periportal fibrosis), F3 (bridging fibrosis), and F4 (cirrhosis).[12] According to the LSM value, the following fibrosis stages were defined: F0 (0–5.9 kPa), F1 (6.0–6.9 kPa), F2 (7.0–9.0 kPa), F3 (9.1–10.3 kPa), and F4 (≥10.4 kPa).[13] LSM values <8 kPa and >12–15 kPa were used to rule out and rule in advanced fibrosis, respectively.[14]

Inclusion Criteria

- Age >18 years.
- Suspected liver parenchymal disease.
- Excessive alcohol consumption.
- Metabolic risk factors.
- No prior liver transplant.
- Willingness and compliance.

Fig. 1: Echosense FibroScan Mini +430—equipment to assess hepatic fibrosis

Fig. 2: FibroScan being performed on patient in real time

Exclusion Criteria

- Pregnancy.
- Age <18 years.
- Noncompliance with study procedures or unwillingness to follow-up.

Statistical Analysis

Data was analyzed using Statistical Package for the Social Sciences (SPSS) version 25. Continuous variables were expressed as mean ± standard deviation (SD) and compared using the *t*-test or analysis of variance (ANOVA); nonparametric tests were applied when appropriate. Categorical variables were summarized as frequencies and percentages and compared using the Chi-squared test or Fisher's exact test. Correlations between continuous variables were assessed using Pearson's or Spearman's correlation coefficients. Diagnostic accuracy of FibroScan for different fibrosis stages was evaluated using receiver operating characteristic (ROC) curve analysis with AUROC, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). A *p*-value <0.05 was considered statistically significant.

Results

A total of 93 patients were enrolled and followed up during the study duration. Clinico-demographic characteristics have been mentioned in (Table 1).

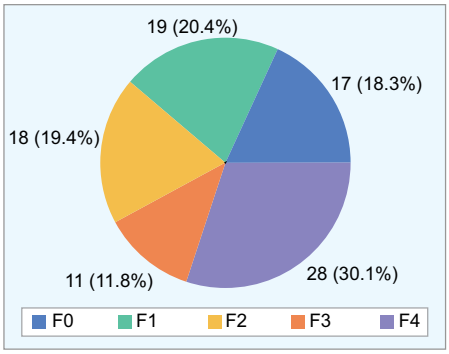

Fig. 3: Fibrosis stage distribution

Fibrosis Assessment

Thirty point one percent of patients had F4 fibrosis. Advanced fibrosis (F3–F4) was present in 41.9% of cases (Fig. 3). Alcohol intake showed a significant association with fibrosis stage ($p = 0.002$). Diabetes was significantly associated with fibrosis stage ($p = 0.008$). The distribution of the different diseases contributing to liver fibrosis has been demonstrated in (Fig. 4). Underlying liver disease type strongly correlated with fibrosis stage ($p < 0.001$). BMI showed a weak but significant correlation with CAP values ($r = 0.21$, $p = 0.043$).

Disease Severity Correlation

Highest LSM values were observed in cirrhosis (28.4 ± 15.3 kPa). Significant differences in LSM values were observed between all disease categories and healthy controls. Strong correlation was noted with liver function parameters, especially bilirubin and AST.

Diagnostic Accuracy

Excellent diagnostic accuracy for cirrhosis (F4) was observed with an AUROC of 0.91.

Table 1: Basic demographics and clinical parameters

Characteristic	*Value*
Total sample size	93
Age (years)	
Mean ± SD	52.3 ± 15.8
Range	18–79
Gender, *n* (%)	
Male	65 (69.9%)
Female	28 (30.1%)
BMI (kg/m^2)	
Mean ± SD	26.5 ± 4.4
Comorbidities, *n* (%)	
None	41 (44.1%)
Diabetes	32 (34.4%)
Hypertension	13 (14.0%)
Others*	7 (7.5%)

*Others: thyroid disease, CKD, autoimmune disease

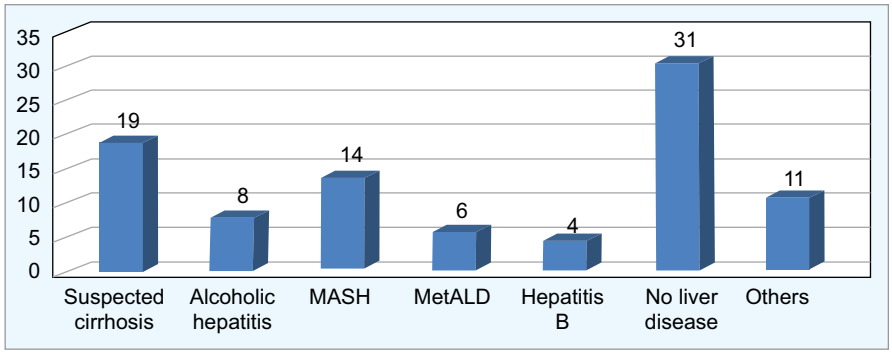

Fig. 4: Liver disease distribution

Good accuracy for significant fibrosis (≥F2) was observed with an AUROC of 0.82. FibroScan® devices cater to a wide sample with a median value of fibrosis assessment requiring a median of 5.3 kPa. Although a value of 14 kPa or more on a FibroScan® device implies a high probability of cirrhotic transformation in chronic diseases of the hepatobiliary system, a lower value may not definitively exclude cirrhosis in the said group of patients, despite high specificity as observed in this study (specificity of 85%).

Discussion

Our study of 93 patients demonstrated that FibroScan® is an effective noninvasive tool for assessing liver fibrosis, with particularly high accuracy in detecting advanced fibrosis and cirrhosis. The study found optimal LSM cut-off values of 7.9 kPa for ≥F2, 9.8 kPa for ≥F3, and 12.5 kPa for F4, with an excellent AUROC of 0.91 for detecting cirrhosis.

Our findings align with several pivotal studies in the field.[15–20] A recent meta-analysis of 50 studies reported similar AUROC values (0.89 for F4), supporting our results. Our cutoff value for cirrhosis (12.5 kPa) is comparable to the widely accepted threshold of 12.8 kPa reported by Castera et al.,[21–26] though slightly lower than the 14.6 kPa suggested in a study on an Asian ethnic cohort.[27]

Disease-specific Correlations

The correlation between LSM and disease severity showed interesting patterns.

Viral Hepatitis

Our mean LSM values for Hepatitis B (14.8 ± 3.1 kPa) are consistent with reported values of 13.9 ± 3.6 kPa in a cohort of 161 patients. The diagnostic accuracy (AUROC 0.82 for ≥F2) compares favorably with reported findings (AUROC 0.81).[28]

MASH/NAFLD

Our results (mean LSM 13.8 ± 5.4 kPa) align with reported findings.[29,30] However, our values are slightly lower than those reported (15.4 ± 6.1 kPa). The influence of BMI on LSM measurements, noted in our study, was also highlighted in previous studies.[31,32]

MetALD

Our findings for alcoholic liver disease (ALD) (16.7 ± 7.2 kPa) are comparable. The higher LSM values in alcoholic cirrhosis align with prior observations.[13,33]

Limitations

Pertaining to Study Design

This was a single-center study with a relatively small sample size, thereby limiting the extrapolation of results to a larger population with diverse clinical features. Liver biopsy is often considered the gold standard modality to assess hepatic fibrosis. Lack of liver biopsy validation in our study for the said participants, secondary to financial constraints, may affect the accuracy of diagnostics in this regard. This study had limited long-term follow-up given the short study duration, which may also limit the accuracy of findings.

Pertaining to Device

Overestimation of fibrosis may occur in certain diseases, such as cholestatic disease, hepatitis, and cardiac cirrhosis, resulting in false-positive values. Additionally, space-occupying lesions in the liver can obscure accurate measurement.

Pertaining to Patient

Multiple patient-related factors may obscure the assessment of liver fibrosis through this technique, such as a BMI >30 kg/m^2, increased age, presence of ascites, and features of metabolic syndrome, which can affect fibrosis determination.

Conclusion

FibroScan® is a highly effective noninvasive tool for assessing liver fibrosis, particularly in detecting advanced stages of cirrhosis, with excellent diagnostic accuracy and significant correlations with various liver disease types. These findings support the integration of FibroScan® into routine clinical practice for improved management of patients with liver disease.

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